CLAIMS

1. The use of a non-live influenza virus antigen preparation in the manufacture of a vaccine formulation for a one-dose intranasal vaccination against influenza, wherein the one-dose vaccination generates an immune response which meets international regulatory requirements for influenza vaccines.

2. The use according to claim 1 wherein the one-dose vaccination achieves at least two out of the three European Union criteria for seroconversion rate, seroprotection rate and seroconversion factor, for the or all strains of influenza present in the vaccine.

3. The use according to claim 2 wherein all three of the European Union criteria are met for the or all strains of influenza represented in the vaccine.

4. The use according to any one of claims 1 to 3 wherein the influenza virus antigen preparation is selected from the group consisting of split virus antigen preparations, subunit antigens, chemically or otherwise inactivated whole virus.

5. The use according to claim 4 wherein the influenza antigen preparation is a split virus antigen preparation.

6. The use according to any one of claims 1 to 5 wherein the formulation comprises at least one surfactant.

7. The use according to claim 6 wherein the surfactant is at least one non-ionic surfactant selected from the group consisting of the octylphenoxypolyethoxyethanols (for example from the commercially available Triton ™ series), polyoxyethylene sorbitan esters (Tween ™ series) and polyoxythylene ethers or esters of general formula (I):

(I) $HO(CH_2CH_2O)_n$-A-R

wherein n is 1-50, A is a bond or –C(O)-, R is C_{1-50} alkyl or phenyl C_{1-50} alkyl, and combinations of two or more of these.

8. The use according to claim 7 wherein the non-ionic surfactant is at least one surfactant selected from the group consisting of t-octylphenoxypolyethoxyethanol (Triton X-100), polyoxyethylene sorbitan monooleate (Tween 80) and laureth 9, or a combination of two or more of these.

9. The use according to claim 8 wherein the vaccine comprises a combination of two of the three non-ionic surfactants, namely polyoxyethylene sorbitan monooleate (Tween 80) and t-octylphenoxypolyethoxyethanol (Triton X-100).

10. The use according to claim 9 wherein the vaccine comprises a combination of all three non-ionic surfactants.

11. The use according to any one of claims 1 to 10 wherein the vaccine further comprises a bile acid or cholic acid, or derivative thereof such as sodium deoxycholate.

12. The use according to any one of claims 1 to11 wherein each dose of the vaccine formulation contains a low dose of haemagglutinin.

13. The use according to claim 12 wherein the haemagglutinin content per influenza strain is about 30 μg or less per dose.

14. The use according to claim 13 wherein the haemagglutinin content per influenza strain is about 15 μg or less per dose.

15. The use according to claim 14 in which the heamagglutinin content is about 7.5 μg or less of haemagglutinin per virus strain per vaccine dose.

16. The use according to any one of claims 1 to 15 wherein the vaccine formulation is in a low volume per dose.

17. The use according to claim 16 wherein the volume per dose is less than 500 µl, or less than 300 µl or not more than about 200 µl per dose.

18. The use according to any one of claims 1 to 17 wherein the vaccine is delivered in a bi-dose format of two sub-doses.

19. The use according to any one of claims 1 to 18, wherein the vaccine does not contain an added immunostimulant.

20. The use according to any one of claims 1 to 18, wherein the vaccine further comprises a non-toxic derivative of lipid A, preferably selected from non-toxic derivatives of monophosphoryl lipid A and diphosphoryl lipid A.

21. The use according to claim 20, wherein the vaccine comprises 3D-MPL.

22. The use according to claim 21, wherein the vaccine comprises 3D-MPL and laureth 9.

23. A method for prophylaxis of influenza infection or disease in a subject which method comprises administering to the subject a single dose of a non-live influenza virus vaccine via a mucosal surface to induce an immune response which meets at least two of the following criteria for all strains of influenza present in the vaccine:

(i) a seroconversion rate of greater than or equal to 40%;

(ii) a seroprotection rate of greater than or equal to 70%; and

(iii) a conversion factor of greater than or equal to 2.5.

24. A method for prophylaxis of influenza infection or disease in a subject which method comprises administering to the subject a single dose of a low HA, non-live influenza virus vaccine via a mucosal surface to induce an immune response which

meets at least two of the following criteria for all strains of influenza present in the vaccine:

(i) a seroconversion rate of greater than or equal to 40%;

(ii) a seroprotection rate of greater than or equal to 70%; and

(iii) a conversion factor of greater than or equal to 2.5.

25. The method according to claim 23 or claim 24 wherein all three of the criteria are met for all strains of influenza present.

26. The method according to any one of claims 23 to 25 wherein the vaccine is delivered intranasally.

27. A pharmaceutical kit comprising an intranasal delivery device and a one-dose vaccine which comprises a non-live influenza virus antigen preparation without an added immunostimulant.

28. A pharmaceutical kit comprising an intranasal delivery device and a one-dose influenza vaccine which generates an immune response that meets the international regulatory requirements for an influenza vaccine.

29. A pharmaceutical kit comprising an intranasal delivery device and a one-dose vaccine which comprises a low HA dose of a non-live influenza virus antigen preparation.

30. The pharmaceutical kit according to any one of claims 27 to 29 wherein the device is a bi-dose delivery device for delivering two sub-doses in a single administration.

31. The pharmaceutical kit according to any one of claims 27 to 30 wherein the device is an intranasal spray device.

32. A method of manufacturing an influenza vaccine for nasal application which method comprises:

(i) providing a split influenza virus preparation produced essentially as for a conventional injected influenza vaccine and comprising at least one non-ionic surfactant;

(ii) optionally adjusting the concentration of the haemagglutinin and/or the concentration of non-ionic surfactant in the preparation;

(iii) filling an intranasal delivery device with a vaccine dose from the split influenza virus preparation, said dose being a suitable volume for intranasal administration, optionally in a bi-dose format.